Interview Summary	Application No.	Applicant(s)	
	09/691,053	Agur	
	Examiner	Art Unit	
	Moran	1631	

All participants (applicant, applicant's representative, PTO personnel):

(1) M. Moran (3)_____.

(2) C. Subramanian (4)_____.

Date of Interview: 1/14/02

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal [copy given to: 1)☐ applicant 2)☒ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: 1-65, 234-331, 466-509

Identification of prior art discussed: BARRY, THALHAMMER-REYERO

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See below

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i)☒ It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

The atty described the inventive system in general terms, but at the examiner's request, agreed to discuss a single subset of claims for this interview. He chose the system for optimizing a treatment protocol for cancer. The exmr and atty discussed the meaning and "inherent" limitations of a computer system, then discussed whether any of the prior art of record teaches a system adapted to generate →

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

MG Moran
Examiner's signature, if required

treatment protocols. The examiner agreed that BARRY teaches "canned" protocols, but does not teach generation of protocols based on individual or population parameters. The examiner stated that the prior art of record does teach equations but does not appear to specifically teach stepwise equations (as recited in claim 238).

No agreement was arrived at for a definition of "realistic".

Proposed amdt for 09/691,053

1. A system for recommending an optimal treatment protocol for an individual comprising:

a system model;

a plurality of treatment protocols;

a system model modifier, wherein said [system model is modified by the] system model modifier is adapted to modify said system model based on parameters specific to the individual; and

a selector to select an optimal treatment protocol from said plurality of treatment protocols based on the modified system model.

2. The system of claim 1 wherein the system model further comprises:

a realistic biological process model; and

a realistic treatment model that models the effects of a treatment on said biological process.

3. The system of claim 2, wherein said biological process model comprises mathematical models for biological processes affecting healthy cell populations and biological processes affecting diseased cell populations with at least one disease.

4. The system of claim 3 wherein said healthy cell populations include bone-marrow cells and host tissue cells that are affected by said treatment model.

5. (amended) The system of claim 3 wherein said diseased cell populations [with at least one disease] is one of cancer cells, and diseased bone-marrow cells [including] wherein the diseased bone-marrow cells could include diseased [Neutrophill] neutrophil cells and diseased [Thrombocyte] thrombocyte cells.

6. The system of claim 2, wherein said treatment models comprise treatment specific processes that affect cell populations.

7. The system of claim 6 wherein said treatment specific process [is] comprises interactions and associated biological processes involving one of a group [comprising] consisting of pharmacokinetic interactions and processes , pharmacodynamic interactions and processes , cytostatic interactions and processes, cytotoxic interactions and processes, and methods of affecting cell biology and causing cell death [, with associated biological processes].

8. The system of claim 1 wherein, said parameters specific to the individual [include] includes one or more selected from a group consisting of parameters related to [the] biological process dynamics, patient specific drug pharmacokinetics [PK], pharmacodynamics [PD], and dynamics of dose-limiting host tissues.

9. The system of claim 8, wherein said parameters related to biological process dynamics comprise age, weight, gender, blood picture, desired

length of treatment protocol, previous reaction to treatment, molecular markers, genetic markers, pathologic specifics and cytologic specifics.

10. The system of claim 1, wherein the selector [incorporates] is adapted to incorporate user-specific parameters in performing selection.

11. The system of claim 10 wherein said [incorporation is done] selector is adapted to incorporate user-specific parameters by using a fitness function.

12. The system of claim 11 wherein said fitness function incorporates at least one parameter selected from a group [comprising] consisting of patient survival, time to death, time to reach a specified disease stage [(including cure)], tumor load, pathogen load, cytotoxicity, side effects, quality of life, cost of treatment, and pain.

13. The system of claim 12, wherein [a user can input] the system is adapted to receive user input for specific coefficients for said at least one parameter and the system is further adapted to adjust the fitness function to satisfy the user's goals.

14. The system of claim 10, wherein the user-specific parameters are based on a user, said user being a medical doctor.

15. The system of claim 10, wherein the user-specific parameters are

based on a user, said user being a scientist.

16. The system of claim 10, wherein the user-specific parameters are based on a user, said user being a drug developer.

17. The system of claim 1 wherein said system is adapted to consider cytotoxic effects during selection of treatment protocols [incorporate cytotoxic effects].

18. The system of claim 1 wherein said system is adapted to consider drug efficacy during selection of treatment protocols [incorporate drug efficacy].

19. The system of claim 1, wherein the selector [performs] is adapted to use operation research methods for the selection [using operation research methods].

20. The system of claim 1, wherein the selector further comprises heuristics, said [heuristics being used to perform searching and selection] selector being adapted to use the heuristics for searching and selection.

21. The system of claim 20 wherein, said heuristics comprise computational feasibility.

22. The system of claim 1 wherein said recommendation is a combination

of disease and treatment strategy, [including types of treatment, e.g. chemotherapy, radiotherapy, surgery, immunotherapy, etc, device, drug or drug combination and treatment schedule and dosage] wherein said treatment strategy includes at least one of types of treatment, device, drug combination, treatment schedule and dosage.

23. The system of claim 1, wherein, said system is adapted to be implemented over a distributed computing system.

24. The system of claim 23, wherein the distributed computing system is the Internet.

25. The system of claim 23, wherein [a user uses the system remotely] the system is adapted to be used remotely by a user.

26. A system for recommending an optimal treatment protocol for a general patient comprising:

a system model;

a plurality of treatment protocols; and

a selector to select an optimal treatment protocol from said plurality of treatment protocols based on the system model.

27. The system of claim 26 wherein the system model further comprises:

a realistic biological process model; and

a realistic treatment model that models the effects of a treatment on said biological process.

28. The system of claim 27, wherein said biological process model comprises mathematical models for biological processes affecting healthy cell populations and biological processes affecting diseased cell populations with at least one disease.

29. The system of claim 28 wherein said healthy cell populations include bone-marrow cells and host tissue cells that are affected by said treatment model.

30. The system of claim 28 wherein said diseased cell populations [with at least one disease] is one of cancer cells, and diseased bone-marrow cells [including] wherein the diseased bone-marrow cells could include diseased [Neutrophill] neutrophil cells and diseased [Thrompocyte] thrombocyte cells.

31. The system of claim 27, wherein said treatment models comprise treatment specific processes that affect cell populations.

32. The system of claim 31 wherein said treatment specific process [is] comprises interactions and associated biological process involving one of a group comprising pharmacokinetic, pharmacodynamic, cytostatic, cytotoxic, and methods of affecting cell biology and causing cell death [, with associated biological processes].

33. The system of claim 26, wherein the selector [incorporates] is adapted to incorporate user-specific parameters in performing selection.

34. The system of claim 33 wherein said [incorporation is done] selector is adapted to incorporate user-specific parameters by using a fitness function.

35. The system of claim 34 wherein said fitness function incorporates at least one parameter selected from a group [comprising] consisting of patient survival, time to death, time to reach a specified disease stage [(including cure)], tumor load, pathogen load, cytotoxicity, side effects, quality of life, cost of treatment and pain.

36. The system of claim 35, wherein [a user can input] the system is adapted to receive user input for specific coefficients for said at least one parameter and the system is further adapted to adjust the fitness function to satisfy the user's goals.

37. The system of claim 33, wherein the user-specific parameters are based on a user, said user being a medical doctor.

38. The system of claim 33, wherein the user-specific parameters are based on a user, said user being a scientist.

39. The system of claim 33, wherein the user-specific parameters are based on a user, said user being a drug developer.

40. The system of claim 26 wherein said system is adapted to consider cytotoxic effects during selection of treatment protocols [incorporate cytotoxic effects].

41. The system of claim 26 wherein said system is adapted to consider drug efficacy during selection of treatment protocols [incorporate drug efficacy].

42. The system of claim 26, wherein the selector is adapted to use operation research methods for [performs] the selection [using operation research methods].

43. The system of claim 26, wherein the selector further comprises heuristics, said [heuristics being used to perform searching and selection] selector being adapted to use the heuristics for searching and selection.

44. The system of claim 43 wherein, said heuristics comprise computational feasibility.

45. The system of claim 26 wherein said recommendation is a combination of disease and treatment strategy, [including types of treatment, e.g. chemotherapy, radiotherapy, surgery, immunotherapy, etc, device, drug or drug

combination and treatment schedule and dosage] wherein said treatment strategy includes at least one of types of treatment, device, drug combination, treatment schedule and dosage.

46. The system of claim 26, wherein, said system is adapted to be implemented over a distributed computing system.

47. The system of claim 46, wherein the distributed computing system is the Internet.

48. The system of claim 46, wherein [a user uses the system remotely] the system is adapted to be used remotely by a user.

49. The system of claim 48, wherein the remote system is a telephone.

50. A system for predicting progression of a biological process in an individual patient under a plurality of treatment protocols, wherein said biological process [could] is be related to healthy or diseased processes, one of said plurality of protocols [including] being no treatment, said system comprising:

a system model;

a plurality of treatment protocols; and

a system model modifier, wherein said [system model is modified by the]

system model modifier is adapted to modify said system model based on parameters specific to the individual.

a predictor to predict the progression of at least one of the disease and the natural biological process under said plurality of treatment protocols based on the modified system model.

51. The system of claim 50 wherein the system model further comprises:

a realistic biological process model; and

a realistic treatment model that models the effects of a treatment on said biological process.

52. The system of claim 51, wherein said biological process model comprises mathematical models for biological processes affecting healthy cell populations and biological processes affecting diseased cell populations [with at least one disease].

53. The system of claim 52 wherein said healthy cell populations include bone-marrow cells and host tissue cells that are affected by said treatment model.

54. The system of claim 52 wherein said diseased cell populations [with at least one disease] is one of cancer cells, and diseased bone-marrow cells [including] wherein the diseased bone-marrow cells could include diseased at least one of [Neutrophill] neutrophil cells and diseased [Thrombocyte] thrombocyte cells.

55. The system of claim 51, wherein said treatment models comprise treatment specific processes that affect cell populations.

56. The system of claim 55 wherein said treatment specific process is interactions and associated biological process involving one of a group comprising pharmacokinetic [PK], pharmacodynamic [PD], drug cytostatics, drug cytotoxics, and methods of affecting cell biology and causing cell death [, with associated biological processes].

57. The system of claim 50 wherein, said parameters specific to the individual include one or more selected from a group consisting of parameters related to [the] biological process dynamics, patient specific drug pharmacokinetics [PK], pharmacodynamics [PD], and dynamics of dose-limiting host tissues.

58. The system of claim 57, wherein said parameters related to biological process' dynamics comprise age, weight, gender, blood picture, desired length of treatment protocol, previous reaction to treatment, molecular markers, genetic markers, pathologic specifics and cytologic specifics.

59. A system for predicting progression of a biological process in a general patient under a plurality of treatment protocols, wherein said biological process [could be] is healthy or diseased processes, said plurality of protocols including no treatment, said system comprising:

a system model;

a plurality of treatment protocols; and

a predictor to predict the progression of the disease or the natural biological process under said plurality of treatment protocols.

60. The system of claim 59 wherein the system model further comprises:

a realistic biological process model; and

a realistic treatment model that models the effects of a treatment on said biological process.

61. The system of claim 60, wherein said biological process model comprises mathematical models for biological processes affecting healthy cell populations and biological processes affecting diseased cell populations with at least one disease.

62. The system of claim 61 wherein said healthy cell populations include bone-marrow cells as well as other host tissue cells that are affected by said treatment model.

63. The system of claim 62 wherein said diseased cell populations [with at least one disease] is one of cancer cells, and diseased bone-marrow cells [including] wherein the diseased bone-marrow cells could include diseased [Neutrophill] neutrophil cells and diseased [Thrombocyte] thrombocyte cells.

64. The system of claim 60, wherein said treatment models comprise

treatment specific processes that affect cell populations.

65. The system of claim 64 wherein said treatment specific process is interactions and associated biological process involving one of a group comprising pharmacokinetic [PK], pharmacodynamic [PD], cytostatic, cytotoxic, and methods of affecting cell biology and causing cell death [, with associated biological processes].

234. A system for recommending an optimal treatment protocol for treating cancer using drugs, [including chemotherapy,] for an individual, said system comprising:

a cancer system model;

a plurality of treatment protocols for treating cancer using chemotherapy;

a system model modifier, wherein said cancer system model is modified by the system model modifier based on parameters specific to the individual; and

a selector to select an optimal treatment protocol from said plurality of treatment protocols based on the modified system model.

235. The system of claim 234 wherein the system model further comprises:

a realistic process model of cancer development; and

a realistic treatment model that models the effects of treating cancer with drugs, including chemotherapy.

236. The system of claim 235 wherein said process model incorporates a distribution of cycling cells and quiescent cells.

237. The system of claim 235 where a tumor cell cycle is divided into at least four compartments G1, S, G2 and M and a quiescent stage is denoted by G0, wherein each of said four compartments is further subdivided into sub-compartments and an ith sub-compartment representing cells of age I in the corresponding compartment, wherein the system is adapted to ensure that cells entering a compartment always enter a first sub-compartment of the compartment.

238. The system of claim 237 wherein the model is adapted to trace [traces] development of cancer cells using a predetermined set of parameters by calculating a number of cells in each subcompartment using stepwise equations.

239. The system of claim 238 wherein the system is adapted to use a probability vector is used to determine a fraction of cells that leaves any subcompartment in a compartment to move to a first subcompartment of the next compartment.

240. The system of claim 238 where the system includes a set control functions that are adapted to uniquely determine an outcome of every single step, wherein said control functions [depend on] comprise age of cells, state of a current population and associated environment.

241. The system of claim 238 wherein the system comprises a model representing a tumor [is modelled as] the model comprising a combination of a

plurality of homogeneous [group] groups of cells, each of said homogeneous [group] groups of cells representing a similarly behaving group of cells distributed between all the cell-cycle compartments.

242. The system of claim 241, wherein the system is adapted to calculate in each step, a number of cells in each sub-compartment of each compartment of each group [is calculated] according to factors including a previous state, parameters of tumor, tumor current microenvironment and drug concentration.

243. The system of claim 242 where spatial structure of the tumor is included in the model.

244. The system of claim 243, wherein the system is adapted to incorporate pharmacokinetic [PK] and pharmacodynamic [PD], cytostatic effects, cytotoxic effects, and other effects on cell disintegration of anticancer drugs [are incorporated into the model].

245. The system of claim 244 wherein the system is adapted to incorporate a dose-limiting toxicity [is incorporated] into the model.

246. (Amended) The system of claim 234 wherein, said parameters specific to the individual comprise parameters related to tumor dynamics, patient specific drug pharmacokinetic [PK], pharmacodynamic and dynamics of dose-limiting host tissues.

247. The system of claim 246, wherein said parameters related to tumor dynamics comprise age, weight, gender, percentage of limiting healthy cells, desired length of treatment protocol, previous reaction to treatment, molecular markers, genetic markers, pathologic specifics and cytologic specifics.

248. A system for predicting the a progression of cancer in individual patients comprising:

a cancer system model;

a plurality of treatment protocols for treating cancer using drugs [, including chemotherapy];

a system model modifier, wherein said cancer system model is modified by the system model modifier based on parameters specific to the individual; and

a predictor to predict the progression of cancer under the plurality of treatment protocols based on the modified system model.

249. The system of claim 248 wherein the system model further comprises:

a realistic process model of cancer development; and

a realistic treatment model that models the effects of treating cancer with drugs, including chemotherapy.

250. The system of claim 249 wherein said process model incorporates a distribution of cycling cells and quiescent cells.

251. The system of claim 249 where a tumor cell cycle is divided into at least four compartments G1, S, G2 and M and a quiescent stage is denoted by G0, wherein each of said four compartments is further subdivided into sub-compartments and an ith sub-compartment representing cells of age in the corresponding compartment, wherein the system is adapted to ensure that cells entering a compartment always enter a first sub-compartment of the compartment.

252. The system of claim 251 wherein the model is adapted to trace [traces] development of cancer cells using a predetermined set of parameters by calculating a number of cells in each subcompartment using stepwise equations.

253. The system of claim 252 wherein the system is adapted to use a probability vector is used to determine a fraction of cells that leaves any subcompartment in a compartment to move to a first subcompartment of the next compartment.

254. The system of claim 252 where the system includes a set control functions that are adapted to uniquely determine an outcome of every single step, wherein said control functions [depend on] comprise age of cells, state of a current population and associated environment.

255. The system of claim 252 wherein the system comprises a model representing a tumor [is modelled as] the model comprising a plurality of homogeneous [group] groups of cells, each of said homogeneous [group] groups of

cells representing a similarly behaving group of cells distributed between all the cell-cycle compartments.

256. The system of claim 255, wherein the system is adapted to calculate in each step, a number of cells in each sub-compartment of each compartment of each group [is calculated] according to factors including a previous state, parameters of tumor, tumor current microenvironment and drug concentration.

257. The system of claim 256 where spatial structure of the tumor is included in the model.

258. The system of claim 257, wherein the system is adapted to incorporate pharmacokinetic [PK] and pharmacodynamic [PD], cytotoxic effects and cytostatic effects of anticancer drugs [are incorporated into the model].

259. The system of claim 258 wherein the system is adapted to incorporate a dose-limiting toxicity [is incorporated] into the model.

260. The system of claim 248 wherein, said parameters specific to the individual comprise parameters related to tumor dynamics, patient specific drug pharmacokinetic [PK], pharmacodynamic, and dynamics of dose-limiting host tissues.

261. The system of claim 260, wherein said parameters related to tumor

dynamics comprise age, weight, gender, percentage of limiting healthy cells, desired length of treatment protocol, previous reaction to treatment, molecular markers, genetic markers, pathologic specifics and cytologic specifics.

262. A system for predicting the a progression of cancer in a general patients comprising:

a cancer system model;

a plurality of treatment protocols for treating cancer using drugs[, including chemotherapy]; and

a predictor to predict the progression of cancer under the plurality of treatment protocols based on the modified system model.

263. The system of claim 262 wherein the system model further comprises:

a realistic process model of cancer development; and

a realistic treatment model that models the effects of treating cancer with drugs, including chemotherapy.

264. The system of claim 263 wherein said process model incorporates a distribution of cycling cells and quiescent cells.

265. The system of claim 263 where a tumor cell cycle is divided into at least four compartments G1, S, G2 and M and a quiescent stage is denoted by G0, wherein each of said four compartments is further subdivided into sub-compartments and an ith sub-compartment representing cells of age I in the

corresponding compartment, wherein the system is adapted to ensure that cells entering a compartment always enter a first sub-compartment of the compartment.

266. The system of claim 265 wherein the model is adapted to trace [traces] development of cancer cells using a predetermined set of parameters by calculating a number of cells in each subcompartment using stepwise equations.

267. The system of claim 266 wherein the system is adapted to use a probability vector is used to determine a fraction of cells that leaves any subcompartment in a compartment to move to a first subcompartment of the next compartment.

268. The system of claim 266 where the system includes a set control functions that are adapted to uniquely determine an outcome of every single step, wherein said control functions [depend on] comprise age of cells, state of a current population and associated environment.

269. The system of claim 266 wherein the system comprises a model representing a tumor [is modelled as] the model comprising a plurality of homogeneous [group] groups of cells, each of said homogeneous [group] groups of cells representing a similarly behaving group of cells distributed between all the cell-cycle compartments.

270. The system of claim 269, wherein the systme is adapted to calculate in

each step, a number of cells in each sub-compartment of each compartment of each group [is calculated] according to factors including a previous state, parameters of tumor, tumor current microenvironment and drug concentration.

271. The system of claim 270 where spatial structure of the tumor is included in the model.

272. The system of claim 271, wherein the system is adapted to incorporate pharmacokinetic [PK] and pharmacodynamic [PD], cytotoxic effects and cytostatic effects of anticancer drugs [are incorporated into the model].

273. The system of claim 272 wherein the system is adapted to incorporate a dose-limiting toxicity [is incorporated] into the model.

274. A method of recommending an optimal treatment protocol for an individual comprising:

creating a system model;

enumerating a plurality of treatment protocols;

modifying the system model based on parameters specific to the individual; [and]

selecting an optimal treatment protocol from said plurality of treatment protocols based on the modified system model and

recommending said optimal treatment.

275. The method of claim 274 wherein the step of creating the system model further comprises:

modelling a biological process; and

realistically modelling effects of a treatment on said biological process.

276. The method of claim 275, wherein said modelling of biological processes is done by [mathematical] mathematically modelling biological processes affecting healthy cell [populationss] populations and mathematically modelling biological processes affecting diseased cell [populationss] populations with at least one disease.

277. The method of claim 276 wherein said healthy cell [populationss] populations include bone-marrow cells and host tissue cells that are affected by said treatment model.

278. The method of claim 276 wherein said diseased cell [populationss] populations [with at least one disease] is one of cancer cells, and diseased bone-marrow cells [including] wherein the diseased bone-marrow cells could include diseased [Neutrophill] neutrophil cells and diseased [Thrompocyte] thrombocyte cells.

279. The method of claim 275, wherein said treatment models comprise treatment specific processes that affect cell[populationss] populations.

280. The method of claim 279 wherein said treatment specific process is interactions and associated biological process involving at least one of a group comprising pharmacokinetic (PK), pharmacodynamic (PD), cytostatic, cytotoxic, and methods of affecting cell biology and causing cell death [, with associated biological processes].

281. The method of claim 274 wherein, said parameters specific to the individual include one or more selected from a group consisting of parameters related to [the] biological process dynamics, patient specific drug pharmacokinetics [PK], pharmacodynamics [PD] and dynamics of dose-limiting host tissues.

282. The method of claim 281, wherein said parameters related to biological process' dynamics comprise age, weight, gender, blood picture, desired length of treatment protocol, previous reaction to treatment, molecular markers, genetic markers, pathologic specifics and cytologic specifics.

283. The method of claim 274, wherein user-specific parameters are used in selecting the optimal treatment.

284. The method of claim 283 wherein a fitness function is used to perform the selection.

285. The method of claim 284 wherein said fitness function incorporates at least one parameter selected from a group consisting patient survival, time to

death, time to reach a specified disease stage (including cure), tumor load, pathogen load, cytotoxicity, side effects, quality of life, cost of treatment and pain.

286. The method of claim 285, wherein a user can input specific coefficients for said at least one parameter to adjust the fitness function to satisfy the user's goals.

287. The method of claim 283, wherein the user-specific parameters are based on a user, said user being a medical doctor.

288. The method of claim 283, wherein the user-specific parameters are based on a user, said user being a scientist.

289. The method of claim 283, wherein the user-specific parameters are based on a user, said user being a drug developer.

290. The method of claim 274 wherein said system is adapted to consider cytotoxic effects during selection of treatment protocols [incorporate cytotoxic effects].

291. The method of claim 274 wherein said system is adapted to consider drug efficacy during selection of treatment protocols [incorporate drug].

292. The method of claim 274, wherein operation research techniques are

used in performing the selection.

293. The method of claim 274, wherein heuristics are used to perform searching and selection.

294. The method of claim 293 wherein, said heuristics comprise computational feasibility.

295. The method of claim 274 wherein said recommendation is a combination of disease and treatment strategy, [including types of treatment, e.g. chemotherapy, radiotherapy, surgery, immunotherapy, etc, device, drug or drug combination and treatment schedule and dosage] wherein said treatment strategy includes at least one of types of treatment, device, drug combination, treatment schedule and dosage.

296. A [Method] method of recommending an optimal treatment protocol for a general patient comprising:

creating a system model;

enumerating a plurality of treatment protocols; [and]

selecting an optimal treatment protocol from said plurality of treatment protocols based on the modified system model; and

recommending said optimal treatment.

297. The method of claim 296 wherein the step of creating the system

model further comprises:

modelling a biological process; and

realistically modelling effects of a treatment on said biological process.

298. The method of claim 297, wherein said modelling of biological processes is done by [mathematical] mathematically modelling biological processes affecting healthy cell [populationss] populations and mathematically modelling biological processes affecting diseased cell [populationss] populations with at least one disease.

299. The method of claim 298 wherein said healthy cell [populationss] populations include bone-marrow cells and host tissue cells that are affected by said treatment model.

300. The method of claim 298 wherein said diseased cell [populationss] populations with at least one disease is one of cancer cells, and diseased bone-marrow cells including diseased [Neutrophill] neutrophil cells and diseased [Thrompocyte] thrombocyte cells.

301. The method of claim 297, wherein said treatment models comprise treatment specific processes that affect cell[populationss] populations.

302. The method of claim 301 wherein said treatment specific process is interactions and associated biological process involving one of a group comprising

pharmacokinetic, pharmacodynamic, cytostatic, cytotoxic, or any other method of affecting cell biology and causing cell death [, with associated biological processes].

303. The method of claim 296, wherein user-specific parameters are used in selecting the optimal treatment.

304. The method of claim 303 wherein a fitness function is used to perform the selection.

305. The method of claim 304 wherein said fitness function incorporates at least one parameter selected from a group [comprising] consisting of patient survival, time to death, time to reach a specified disease stage [(including cure)], tumor load, pathogen load, cytotoxicity, side effects, quality of life, cost of treatment and pain.

306. The method of claim 305, wherein a user can input specific coefficients for said at least one parameter to adjust the fitness function to satisfy the user's goals.

307. The method of claim 303, wherein the user-specific parameters are based on a user, said user being a medical doctor.

308. The method of claim 303, wherein the user-specific parameters are based on a user, said user being a scientist.

309. The method of claim 303, wherein the user-specific parameters are based on a user, said user being a drug developer.

310. The method of claim 296 wherein said system is adapted to consider cytotoxic effects during selection of treatment protocols [incorporate cytotoxic effects].

311. The method of claim 296 wherein said system is adapted to consider drug efficacy during selection of treatment protocols [incorporate drug efficacy].

312. The method of claim 296, wherein operation research techniques are used in performing the selection.

313. The method of claim 296, wherein heuristics are used to perform searching and selection.

314. The method of claim 313 wherein, said heuristics comprise computational feasibility.

315. The method of claim 296 wherein said recommendation is a combination of disease and treatment strategy, [including types of treatment, e.g. chemotherapy, radiotherapy, surgery, immunotherapy, etc, device, drug or drug combination and treatment schedule and dosage] wherein said treatment strategy includes at least one of types of treatment, device, drug combination, treatment

schedule and dosage.

316. A method of predicting progression of a biological process in an individual patient under a plurality of treatment protocols, wherein said biological process could be related to healthy or diseased processes, said plurality of protocols including no treatment, said method comprising:

creating a system model;

enumerating a plurality of treatment protocols; and

modifying the system model based on parameters specific to the individual.

selecting an optimal treatment protocol from said plurality of treatment protocols based on the modified system model ; and

predicting said progression based on the modified system model and selected optimal treatment protocol.

317. The method of claim 316 wherein the step of creating a system model further comprises:

realistically modelling a biological process; and

realistically modelling the effects of the treatment on said biological process.

318. The method of claim 317, wherein said step of modelling a biological process comprises creating a mathematical model for biological processes affecting healthy cell populations and creating a biological processes affecting diseased cell populations with at least one disease.

319. The method of claim 318 wherein said healthy cell populations include bone-marrow cells and host tissue cells that are affected by said treatment model.

320. The method of claim 318 wherein said diseased cell [populationss] populations with at least one disease is one of cancer cells, and diseased bone-marrow cells[including] wherein the diseased bone-marrow cells could include diseased [Neutrophill] neutrophil cells and diseased [Thrombocyte] thrombocyte cells.

321. The method of claim 317, wherein said treatment models comprise treatment specific processes that affect cell[populationss] populations.

322. The method of claim 321 wherein said treatment specific process is interactions and associated biological process involving one of a group comprising pharmacokinetic [PK], pharmacodynamic [PD], drug cytostatics, drug cytotoxics, or any other method of affecting cell biology and causing cell death [, with associated biological processes].

323. The method of claim 316 wherein, said parameters specific to the individual include one or more selected from a group consisting of parameters related to [the] biological process dynamics, patient specific drug pharmacokinetics [PK], pharmacodynamics [PD], and dynamics of dose-limiting host tissues.

324. The method of claim 323, wherein said parameters related to biological process' dynamics comprise age, weight, gender, blood picture, desired length of treatment protocol, previous reaction to treatment, molecular markers, genetic markers, pathologic specifics and cytologic specifics.

325. A method of predicting progression of a biological process in a general patient under a plurality of treatment protocols, wherein said biological process could be related to healthy or diseased patient, said plurality of protocols including no treatment, said method comprising:

creating a system model;

enumerating a plurality of treatment protocols; [and]

selecting an optimal treatment protocol from said plurality of treatment protocols based on the modified system model; and

predicting said progression based on the modified system model and selected optimal treatment protocol.

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326. The method of claim 325 wherein the step of creating a system model further comprises:

realistically modelling a biological process; and

realistically modelling the and the effects of the treatment on said biological process.

327. The method of claim 326, wherein said step of modelling a biological

process comprises creating a mathematical model for biological processes affecting healthy cell populations and creating a biological processes affecting cell populations with at least one disease.

328. The method of claim 327 wherein said healthy cell populations include bone-marrow cells and host tissue cells that are affected by said treatment model.

329. The method of claim 327 wherein said cell populations with at least one disease is one of cancer cells, and diseased bone-marrow cells [including] wherein the diseased bone-marrow cells could include at least one of diseased [Neutrophill] neutrophil cells and diseased [Thrombocyte] thrombocyte cells.

330. The method of claim 326, wherein said treatment models comprise treatment specific processes that affect cell populations.

331. The method of claim 330 wherein said treatment specific process is interactions and associated biological process involving one of a group comprising pharmacokinetic [PK], pharmacodynamic [PD], cytostatic, cytotoxic, and methods of affecting cell biology and causing cell death [, with associated biological processes].

466. A method for recommending an optimal treatment protocol for treating cancer using drugs , including chemotherapy, for an individual, said method comprising:

creating a cancer system model;

enumerating a plurality of treatment protocols for treating cancer using drugs [, including chemotherapy];

modifying the system model based on parameters specific to the individual; [and]

selecting an optimal treatment protocol from said plurality of treatment protocols based on the modified system model; and

recommending said optimal treatment.

467. The method of claim 466 wherein the system model further comprises:

a realistic process model of cancer development; and

a realistic treatment model that models the effects of treating cancer with drugs, including chemotherapy.

468. The method of claim 467 wherein said process model incorporates a distribution of cycling cells and quiescent cells.

469. The method of claim 467 where a tumor cell cycle is divided into at least four compartments G1, S, G2 and M and a quiescent stage is denoted by G0, wherein each of said four compartments is further subdivided into sub-compartments and an ith sub-compartment representing cells of age I in the corresponding compartment, wherein cells entering a compartment always enter a first sub-compartment of the compartment.

470. The method of claim 469 wherein the model traces development of

cancer cells using a predetermined set of parameters by calculating a number of cells in each subcompartment using stepwise equations.

471. The method of claim 470 wherein a probability vector is used to determine a fraction of cells that leaves any subcompartment in a compartment to move to a first subcompartment of the next compartment.

472. The method of claim 470 where a set control functions uniquely determine an outcome of every single step, wherein said control functions [depend on] comprise age of cells, state of a current population and associated environment.

473. The method of claim 470 wherein a tumor is modelled as a combination of a plurality of homogeneous [group] groups of cells, each of said homogeneous [group] groups of cells representing a similarly behaving group of cells distributed between all the cell-cycle compartments.

474. The method of claim 473, wherein in each step, a number of cells in each sub-compartment of each compartment of each group is calculated according to factors including a previous state, parameters of tumor, tumor current microenvironment and drug concentration.

475. The method of claim 474 where spatial structure of the tumor is included in the model.

476. The method of claim 475, wherein pharmacokinetic [PK] and pharmacodynamic [PD],, cytotoxic effects,cytostatic effects and other effects on cell disintegration of anticancer drugs are incorporated into the model.

477. The method of claim 476 wherein a dose-limiting toxicity is incorporated into the model.

478. The method of claim 466 wherein, said parameters specific to the individual comprise parameters related to tumor dynamics, patient specific drug pharmacokinetic [PK], pharmacodynamic, and dynamics of dose-limiting host tissues.

479. The method of claim 478, wherein said parameters related to tumor dynamics comprise age, weight, gender, percentage of limiting healthy cells, desired length of treatment protocol, previous reaction to treatment, molecular markers, genetic markers, pathologic specifics and cytologic specifics.

480. A method of predicting a progression of cancer in an individual, said method comprising:

creating a cancer system model;

enumerating a plurality of treatment protocols for treating cancer using drugs, including chemotherapy;

modifying the system model based on parameters specific to the individual;

[and]

selecting an optimal treatment protocol from said plurality of treatment protocols based on the modified system model; and

predicting said progression based on the modified system model and selected optimal treatment protocol.

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481. The method of claim 480 wherein the system model further comprises:

a realistic process model of cancer development; and

a realistic treatment model that models the effects of treating cancer with drugs [, including chemotherapy].

482. The method of claim 481 wherein said process model incorporates a distribution of cycling cells and quiescent cells.

483. The method of claim 481 where a tumor cell cycle is divided into at least four compartments G1, S, G2 and M and a quiescent stage is denoted by G0, wherein each of said four compartments is further subdivided into sub-compartments and an ith sub-compartment representing cells of age I in the corresponding compartment, wherein cells entering a compartment always enter a first sub-compartment of the compartment.

484. The method of claim 483 wherein the model traces development of cancer cells using a predetermined set of parameters by calculating a number of

cells in each subcompartment using stepwise equations.

485. The method of claim 484 wherein a probability vector is used to determine a fraction of cells that leaves any subcompartment in a compartment to move to a first subcompartment of the next compartment.

486. The method of claim 484 where a set control functions uniquely determine an outcome of every single step, wherein said control functions [depend on] comprise age of cells, state of a current population and associated environment.

487. The method of claim 484 wherein a tumor is modelled as a combination of a plurality of homogeneous [group] groups of cells, each of said homogeneous [group] groups of cells representing a similarly behaving group of cells distributed between all the cell-cycle compartments.

488. The method of claim 487, wherein in each step, a number of cells in each sub-compartment of each compartment of each group is calculated according to factors including a previous state, parameters of tumor, tumor current microenvironment and drug concentration.

489. The method of claim 488 where spatial structure of the tumor is included in the model.

490. The method of claim 489, wherein pharmacokinetic [PK] and pharmacodynamic [PD], cytotoxic and other cell disintegration effects , and cytostatic effects of anticancer drugs are incorporated into the model.

491. The method of claim 490 wherein a dose-limiting toxicity is incorporated into the model.

492. The method of claim 480 wherein, said parameters specific to the individual comprise parameters related to tumor dynamics, patient specific drug pharmacokinetic [PK], pharmacodynamic, and dynamics of dose-limiting host tissues.

493. The method of claim 492, wherein said parameters related to tumor dynamics comprise age, weight, gender, percentage of limiting healthy cells, desired length of treatment protocol, previous reaction to treatment, molecular markers, genetic markers, pathologic specifics and cytologic specifics.

494. A method of predicting a progression of cancer in a general patient, said method comprising:

creating a cancer system model;

enumerating a plurality of treatment protocols for treating cancer using drugs[, including chemotherapy]; [and]

selecting an optimal treatment protocol from said plurality of treatment protocols based on the modified system model; and

predicting said progression based on the modified system model and selected optimal treatment protocol.

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495. The method of claim 494 wherein the system model further comprises:

a realistic process model of cancer development; and

a realistic treatment model that models the effects of treating cancer with drugs, including chemotherapy.

496. The method of claim 495 wherein said process model incorporates a distribution of cycling cells and quiescent cells.

497. The method of claim 495 where a tumor cell cycle is divided into at least four compartments G1, S, G2 and M and a quiescent stage is denoted by G0, wherein each of said four compartments is further subdivided into sub-compartments and an ith sub-compartment representing cells of age I in the corresponding compartment, wherein cells entering a compartment always enter a first sub-compartment of the compartment.

498. The method of claim 497 wherein the model traces development of cancer cells using a predetermined set of parameters by calculating a number of cells in each subcompartment using stepwise equations.

499. The method of claim 498 wherein a probability vector is used to

determine a fraction of cells that leaves any subcompartment in a compartment to move to a first subcompartment of the next compartment.

500. The method of claim 498 where a set control functions uniquely determine an outcome of every single step, wherein said control functions [depend on] comprise age of cells, state of a current population and associated environment.

501. The method of claim 498 wherein a tumor is modelled as a combination of a plurality of homogeneous [group] groups of cells, each of said homogeneous [group] groups of cells representing a similarly behaving group of cells distributed between all the cell-cycle compartments.

502. The method of claim 501, wherein in each step, a number of cells in each sub-compartment of each compartment of each group is calculated according to factors including a previous state, parameters of tumor, tumor current microenvironment and drug concentration.

503. The method of claim 502 where spatial structure of the tumor is included in the model.

504. The method of claim 503, wherein pharmacokinetic [PK] and pharmacodynamic [PD], cytotoxic effects and cytostatic effects of anticancer drugs are incorporated into the model.

505. The method of claim 504 wherein a dose-limiting toxicity is incorporated into the model.

506. A computer program product, including a computer readable medium, said program product comprising a set of instruction to enable a computer system to aid in recommending an optimal treatment protocol for an individual comprising:

a system model code;

treatment protocol code for a plurality of treatment protocols;

a system model modifier code , wherein said system model is modified by the system model modifier based on parameters specific to the individual; and

a selector code to select an optimal treatment protocol from said plurality of treatment protocols based on the modified system model.

507. The computer program product of claim 506 wherein the system model code further comprises:

a realistic biological process model code; and

a realistic treatment model code that enables a computer to model the effects of a treatment on the biological process.

508. A computer program product, including a computer readable medium, said program product comprising a set of instructions to enable a computer system to aid in recommending an optimal treatment protocol for a general patient comprising:

a system model code;

treatment protocol code for a plurality of treatment protocols; and

a selector code to select an optimal treatment protocol from said plurality of treatment protocols based on the modified system model.

509. The computer program product of claim 508 wherein the system model code further comprises:

a realistic biological process model code; and

a realistic treatment model code that enables a computer to model the effects of a treatment on the biological process.